JC18 Rec'd PCT/PTO 03 DEC 2001

<table>
<tr><td colspan="2">FORM PTO-1390
REV: 5-93
US DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</td><td>ATTORNEYS DOCKET NUMBER
P01,0442
U.S.APPLICATION NO. (if known, see 37 CFR 1.5)
10/009469</td></tr>
<tr><td>INTERNATIONAL APPLICATION NO.
PCT/SE00/01025</td><td>INTERNATIONAL FILING DATE
MAY 22, 2000</td><td>PRIORITY DATE CLAIMED
JUNE 3, 1999</td></tr>
<tr><td colspan="3">TITLE OF INVENTION: "METHOD AND CIRCUIT FOR MONITORING AN OSCILLATOR IN A MEDICAL IMPLANT" (AS AMENDED)</td></tr>
<tr><td colspan="3">APPLICANT(S) FOR DO/EO/US: SVEN-ERIK HEDBERG and JONAS ANDERSSON</td></tr>
</table>

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ■ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. □ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ■ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
4. ■ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ■ A copy of International Application as filed (35 U.S.C. 371(c)(2))
   a. ■ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. □ has been transmitted by the International Bureau.
   c. □ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ■ A translation of the International Application into English (35 U.S.C. 371(c)(2).
7. ■ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
   a. □ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. □ have been transmitted by the International Bureau.
   c. ■ have not been made; however, the time limit for making such amendments has NOT expired.
   d. □ have not been made and will not be made.
8. □ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ■ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). **(UNSIGNED)**
10. ■ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ■ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; **(PTO 1449, Prior Art, Search Report)**.
12. □ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ■ A FIRST preliminary amendment.
    □ A SECOND or SUBSEQUENT preliminary amendment.
14. ■ A substitute specification.
15. □ A change of power of attorney and/or address letter.
16. ■ Other items or information:
    a. ■ Submission of Informal Drawings and Request For Approval of Drawing Changes - Priority Document
    b. ■ **EXPRESS MAIL #EJ552525118**

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U.S.APPLICATION NO. (if known, see 37 C.F.R. 1.5) 10/009469	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER

17. ■ The following fees are submitted:				CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO and International Search Report not prepared by EPO or JPO .... $1040.00 No international preliminary examination fee USPTO (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO .... $890.00 International preliminary examination fee USPTO (37 C.F.R. 1.482) not paid to USPTO but international search fee fee paid to USPTO (37 C.F.R. 1.445(a)(2) .... $740.00 International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but all claimd did not satisfy provisions of PCT Article 33(1)-(4) .... $710.00 International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $100.00					
ENTER APPROPRIATE BASIC FEE AMOUNT =				$ 890.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).				$	
Claims	Number Filed	Number Extra	Rate		
Total Claims	26 - 20 =	6	X $ 18.00	$ 108.00	
Independent Claims	2 - 3 =	0	X $ 84.00	$	
Multiple Dependent Claims			$280.00 +	$	
TOTAL OF ABOVE CALCULATIONS =				$ 998.00	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)				$	
SUBTOTAL =				$ 998.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	
TOTAL NATIONAL FEE =				$ 998.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property **(see separate envelope)** +				$	
TOTAL FEES ENCLOSED =				$ 998.00	
				Amount to be refunded	$
				charged	$

a. ■ A check in the amount of **$ 998.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. ________ in the amount of $ ______ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **501519**. A duplicate copy of this sheet is enclosed.

d ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

Steven H. Noll
NAME

28,982
Registration Number

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BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

AMENDMENT "A" PRIOR TO ACTION AND SUBMISSION OF SUBSTITUTE SPECIFICATION

APPLICANTS:	Hedberg et al.
ATTORNEY DOCKET NO.	P01,0442
INTERNATIONAL APPLICATION NO:	PCT/SE00/01025
INTERNATIONAL FILING DATE:	May 22, 2000

INVENTION: "MEDICAL IMPLANT"

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT application as follows, and requests entry of the Amendment prior to examination in the United States National Examination Phase.

IN THE TITLE:

Please cancel the present title and substitute the following title therefor:

--"METHOD AND CIRCUIT FOR MONITORING AN OSCILLATOR IN A MEDICAL IMPLANT"--

IN THE SPECIFICATION:

Please enter the substitute specification submitted herewith pursuant to 37 C.F.R. §1.125(b). A marked up copy of the substitute specification showing all changes is also submitted herewith. The substitute specification does not contain any new matter.

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IN THE DRAWINGS:

Please amend each of Figures 1, 2, 3, 4 and 5 as shown on the drawing copies marked in red attached to the Request for Approval of Drawing Changes, filed simultaneously herewith.

IN THE CLAIMS:

On amended sheet 16, cancel "CLAIMS" at the top of the page, and substitute:

--**WE CLAIM AS OUR INVENTION:**-- therefor.

Cancel claims 1-26 on amended sheets 16-22, and substitute the following claims therefor:

27. A medical implant comprising:

an oscillator which emits an oscillator output, said oscillator being designed to emit a specified oscillator output;

a measuring arrangement adapted to interact with a living subject to obtain a physiological parameter having a time component, said measuring arrangement generating an electrical signal dependent on said time component; and

an oscillator monitoring circuit connected to said oscillator and to said measuring arrangement, said oscillator monitoring circuit receiving said oscillator output and said electric signal respectively from said oscillator and said measuring arrangement and, using said electric signal, identifying a deviation of said oscillator output from said specified oscillator output and, if said deviation is identified, emitting a deviation signal indicating identification of said deviation.

28. A medical implant as claimed in claim 27 wherein said oscillator monitoring circuit comprises a signal processor for processing said electric signal and said oscillator output to generate an oscillator status signal, and a comparator supplied with said status signal which compares said status signal to a reference signal representing said specified oscillator output, to generate said deviation signal.

29. A medical implant as claimed in claim 28 wherein said measuring arrangement includes a sensor for sensing said physiological parameter.

30. A medical implant as claimed in claim 29 wherein said sensor comprises cardiac electrodes adapted to detect cardiac electrical activity, as said physiological parameter, said cardiac electrodes generating an intracardiac electrogram representing said cardiac electrical activity, said intracardiac electrogram containing said time component.

31. A medical implant as claimed in claim 30 wherein said measuring arrangement comprises a detector connected to said sensor for detecting a QRS complex and a T-wave in said intracardiac electrogram, said detector generating said electric signal, and said electric signal comprising a QRS detection signal and a T-wave detection signal.

32. A medical implant as claimed in claim 31 wherein said oscillator emits periodic pulses as said oscillator output, and wherein said signal processor comprises a counter connected to said detector for receiving said QRS detection signal and said T-wave detection signal therefrom, and connected to said oscillator for receiving said periodic pulses therefrom, said counter counting a number of said periodic pulses received between reception by said counter of said QRS detection signal and reception by said counter of said T-wave detection signal, and emitting said number as said oscillator status signal.

33. A medical implant as claimed in claim 30 wherein said oscillator emits periodic pulses as said oscillator output, and wherein said measuring arrangement comprises a detector connected to said sensor for detecting a QRS complex in said intracardiac electrogram, said detector generating said electric signal, and said electric signal comprising a QRS signal indicating a beginning and an end of said QRS complex, and said signal processor comprising a counter connected to said detector for receiving said QRS signal therefrom, and to said oscillator for receiving said periodic pulses therefrom, said counter counting a number of said periodic pulses received by said counter between said beginning and said end of said QRS complex, and emitting said number as said oscillator status signal.

34. A medical implant as claimed in claim 30 wherein said measuring arrangement comprises a detector connected to said sensor for detecting a QRS complex, said detector generating said electric signal and said electric signal having an amplitude during said QRS complex, and wherein said signal processor includes an integrator connected to said detector for receiving said electric signal therefrom, said integrator integrating said amplitude during said QRS complex to obtain an integration result, and emitting said integration result as said oscillator status signal.

35. A medical implant as claimed in claim 29 wherein said sensor comprises a microphone for detecting periodic heart sounds as said physiological parameter, and for converting said periodic heart sounds into an electric periodic sound signal having said time component, and wherein said measuring arrangement comprises a detector connected to said microphone for detecting a selected characteristic of said electric periodic sound signal, said detector generating said electric signal and said electric signal representing said characteristic, and wherein said signal processor generates said status signal dependent on said characteristic in said electric signal.

36. A medical implant as claimed in claim 28 wherein said comparator compares said oscillator status signal with a reference signal representing a threshold range, and emits said deviation signal if said oscillator status signal is outside of said threshold range.

37. A medical implant as claimed in claim 28 further comprising a deviation handling circuit connected to said oscillator monitoring circuit for receiving said deviation signal therefrom, said deviation handling circuit initiating predetermined remedial action upon receipt of said deviation signal.

38. A medical implant as claimed in claim 37 wherein said oscillator emits periodic pulses as said oscillator output, and wherein said medical implant includes at least one operating component normally supplied with said periodic pulses from said oscillator, and wherein said deviation handling circuit comprises:

a back-up oscillator which emits periodic pulses, said periodic pulses from said back-up oscillator normally being isolated from said operating component; and

switching circuitry connected to said oscillator and to said back-up oscillator for, upon said deviation handling circuit receiving said deviation signal, disconnecting said oscillator from said operating component and connecting said back-up oscillator to said operating component so that said operating component receives said periodic pulses from said back-up oscillator.

39. A medical implant as claimed in claim 38 wherein said back-up oscillator is designed to emit a specified back-up oscillator output, including said periodic pulses, and wherein said oscillator monitoring circuit is connected to said back-up oscillator and identifies a further deviation between said back-up oscillator output and said specified back-up oscillator output, and generates a further deviation signal if said further deviation is identified, said further deviation signal being supplied to said deviation handling circuit and said deviation handling circuit initiating further remedial

action involving said back-up oscillator upon receipt of said further deviation signal.

40. A medical implant as claimed in claim 38 wherein said back-up oscillator is an RC oscillator.

41. A medical implant as claimed in claim 37 wherein said deviation handling circuit includes an alarm unit which emits an alarm signal upon receipt of said deviation signal.

42. A medical implant as claimed in claim 27 wherein said oscillator is a crystal oscillator.

43. A method for monitoring a functioning of an oscillator in a medical implant, comprising the steps of:

obtaining at least one physiological parameter from a living subject in whom said medical implant is implanted, said physiological parameter containing a time component; and

monitoring functioning of an oscillator in said medical implant, and using said physiological parameter for monitoring said functioning of said oscillator.

44. A method as claimed in claim 43 wherein the step of monitoring functioning of said oscillator comprises detecting a deviation in the functioning of said oscillator from a specified functioning of said oscillator; and

generating a deviation signal if said deviation is identified.

45. A method as claimed in claim 44 wherein the step of obtaining said physiological parameter comprises:

sensing said physiological parameter with a sensor adapted for interacting with said subject; and

generating an electrical signal based on said physiological parameter;

and wherein the step of identifying said deviation comprises:

processing said electric signal to obtain an oscillator status signal; and

comparing said oscillator status signal with a reference signal representing said specified functioning of said oscillator.

46. A method as claimed in claim 45 wherein the step of sensing said physiological parameter comprises sensing cardiac electrical activity, and wherein the step of generating an electric signal comprises generating an intracardiac electrogram as said electric signal, said intracardiac electrogram containing said time component.

47. A method as claimed in claim 46 wherein said oscillator emits periodic pulses as an oscillator output, and wherein the step of processing said electric signal comprises:

detecting a QRS complex in said intracardiac electrogram;

detecting a T-wave in said intracardiac electrogram;

counting a number of said periodic pulses emitted by said oscillator between detection of said QRS complex and detection of said T-wave; and

using said number as said oscillator status symbol.

48. A method as claimed in claim 45 wherein the step of comparing said oscillator status signal with a reference signal comprises comparing said oscillator status signal to two reference signals representing a reference range; and

generating said deviation signal if said oscillator status signal is outside of said reference range.

49. A method as claimed in claim 44 comprising automatically initiating remedial action in said medical implant to obtain an oscillator output conforming to said specified functioning of said oscillator.

50. A method as claimed in claim 49 wherein the step of initiating remedial action comprises:

activating a previously non-activated back-up oscillator which generates said specified functioning of said oscillator; and

disconnecting said oscillator in said medical implant from components in said medical implant in need of said specified functioning of said oscillator, and connecting said back-up oscillator to said components.

51. A method as claimed in claim 50 comprising the steps of:

monitoring said back-up oscillator and generating a further deviation signal if functioning of said back-up oscillator deviates from said specified functioning of said oscillator; and

automatically initiating further remedial action if said further deviation signal is generated.

52. A method as claimed in claim 49 wherein the step of automatically initiating remedial action includes generating an alarm signal.

IN THE ABSTRACT:

Please add an Abstract as set forth on separately numbered page 23, attached hereto.

REMARKS:

The present Amendment makes editorial changes in the title, specification, drawings, and claims, and adds an Abstract, to conform the present PCT application to the requirements of United States patent practice.

No deviation in the claim language of the claims presented herein compared to cancelled claims 1-26 has been made for the purpose of distinguishing any of the claims presented herein over the teachings of the prior art of record. Accordingly, no change in the claim language is considered by the Applicants as a surrender of any of the subject matter encompassed within the scope of cancelled claims 1-26.

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4/PRTS

SUBSTITUTE SPECIFICATION

SPECIFICATION

TITLE

"METHOD AND CIRCUIT FOR MONITORING AN OSCILLATOR IN A MEDICAL IMPLANT"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to the field of medical implants. More specifically, the present invention relates to a medical implant of the type having an oscillator monitoring circuit for monitoring the functioning of an oscillator in the medical implant, and a method for monitoring the functioning of an oscillator in a medical implant, such as a heart stimulator.

Description of the Prior Art

For modern electronic circuits, it is generally essential to provide an accurate clocking signal in order to synchronize the different electronic functions of the circuit. Generally, a single master timing source, such as an oscillator, is used to produce a periodic signal at a fixed frequency. An accurate clock signal is imperative for a proper functioning of the electronic circuit. If the frequency of the periodic signal deviates from its predetermined frequency, the circuit will not function in the intended manner.

Within the field of medical implants, i.e. heart stimulators, the master timing source is generally an oscillator. Heart stimulators are life supporting, therapeutic medical devices that are surgically implanted and remain within a person's body for years. Thus, a need exists for monitoring and checking

the master oscillator of the heart stimulator to determine if the frequency of the oscillator periodic signals deviates from its predetermined clock frequency and to handle such a deviation if it occurs.

United States Patent No. 4,590,941 discloses a cardiac pacer having stimulating logic for producing an output stimulating signal, the stimulating logic including a crystal oscillator and a digital circuit serving as the pacing logic of the pacer. The pacer further has a continuously operating RC oscillator and a frequency checking circuit. The RC oscillator is an emergency oscillator continuously producing an output at a predetermined acceptable frequency and a predetermined pulse width. The crystal frequency is tested by the frequency checking circuit using the output of the RC oscillator. The pacer further has a gating means for substituting the output of the RC oscillator for the output of the stimulating logic upon detection of failure of the crystal oscillator.

Hence, the reference parameter used for continuously testing the frequency of the crystal oscillator is the output frequency of the RC oscillator. This requires a continuous operation of the RC oscillator. Furthermore, the frequency checking circuit requires a reliable output from the RC oscillator in order to provide a safe and accurate result. Otherwise, the frequency of the crystal oscillator could be considered to deviate from the correct frequency when, in fact, it is the frequency of the RC oscillator that deviates from the predetermined frequency.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a method, and a medical implant using the method, for detecting with improved reliability a frequency deviation of the output frequency of an oscillator in a medical implant.

The above object is achieved in accordance with the principles of the present invention in a method and circuit for monitoring an oscillator in a medical implant wherein at least one physiological parameter, having a time component, is obtained from a subject in whom the medical implant is implanted, and wherein an electrical signal is generated that is related to the time component, and wherein this electrical signal is used as an indicator of a deviation of the functioning of the oscillator from an intended or specified functioning of the oscillator.

The invention is based on using a physiological parameter emanating from the human body for monitoring the status of the output frequency of a timing circuit in a medical implant. Hence, deviations in the output frequency of the timing circuit are detected by using the physiological parameter as a reference. Preferably, the timing circuit is an oscillator.

By using a physiological parameter for detecting a deviation in the output frequency of an oscillator, use is made of a parameter that is always present, i.e. the physiological parameter can be used for detecting a frequency deviation regardless of whether there is a fault in the electronic circuitry or not. This might not always be the case when a parameter

obtained from within the electronic circuitry is used for the deviation detection. In fact, a deviation in the output frequency of a main oscillator in an electronic circuit, can cause resulting effects in the electronic circuitry making components within the circuitry unsuitable, or unusable, for providing a reference parameter for the monitoring.

Furthermore, the problem described in relation to prior art regarding the risk of misinterpreting the result, i.e. the output frequency one oscillator being considered to deviate when the deviation occurs in the output frequency of the other oscillator, is eliminated according to the present invention. This is due to the fact that the monitoring of an oscillator does not involve any other oscillator that might be present in the medical implant.

The physiological parameter used for monitoring the output frequency of the oscillator contains a time component. The time component of the physiological parameter is used for monitoring deviation of the frequency from a permitted value or range.

As is known to a person skilled in the art, any physiological parameter varies over time. Therefore, an exact time value can not be obtained from a physiological parameter. However, the typical oscillator used as a main oscillator in a medical implant is a crystal oscillator, which is calibrated before encapsulation by mechanical trimming. It is well known that, if the output frequency of a crystal oscillator deviates from its intended frequency, it deviates drastically, the output frequency for instance changing to zero or multiples of the intended frequency. Thus, a physiological parameter can be

used for monitoring the status of an oscillator, even though the parameter varies slightly over time.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of a medical implant having an oscillator monitoring circuit according to the present invention.

Figure 2 is a block diagram of the measuring circuit shown in Figure 1.

Figure 3 is a block diagram of the monitoring circuit shown in Figure 1.

Figure 4 is a block diagram of a specific embodiment of the present invention.

Figure 5 is a block diagram of a watch dog circuit according to the embodiment shown in Figure 4.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 is a block diagram of a medical implant 1 having an oscillator 2, an oscillator monitoring circuit 10, a measuring circuit 20 and a deviation handling circuit 30. As is apparent to the person skilled in the art, a medical implant, i.e. a heart stimulator, contains and is connected to a number of additional elements that are essential for the in tended function of the implant, e.g. a pulse generator, telemetry means, etc. However, the functions of these elements are well known within the art and the illustration and description thereof are therefore omitted. Thus, only parts of the

medical implant directly related to the present invention are illustrated and described herein.

As illustrated in Figure 2, the measuring circuit 20 preferably has a sensor 21, for sensing, or recording, a chosen physiological parameter P, and a detector 25 for detecting characteristics of the chosen physiological parameter P. The sensor type can be chosen among several alternatives and is dependent on the chosen physiological parameter P. The sensor 21 is connected to the detector 25, but is not necessarily contained within the medical implant 1, contrary to what is illustrated in Figure 1. According to embodiments of the invention, the sensor 21 is situated externally of the medical implant and is connected to the medical implant via electric leads 20 (not shown).

The detector 25 is arranged for detecting characteristics of the physiological parameter P having the chosen time component, the characteristics being dependent on the type of parameter sensed, and for generating an electric signal E containing or being related to these characteristics. The sensor 21 and the detector 25 do not necessarily have to be separate units, instead they can be formed as a single unit for sensing the physiological parameter P and for generating the electric signal B.

With reference to Figure 3, the oscillator monitoring circuit 10 preferably has a signal processor 11, receiving the electric signal E and oscillator output frequency F (i.e. the periodic pulses produced by the oscillator), and comparator I5, receiving an oscillator status signal S supplied

by the signal processing circuit and a predetermined reference signal Ref, which can be in the form of a value, range, or a template. Preferably, the electric signal B representative of the physiological parameter P is used by the signal processing circuit for generating an oscillator status signal S that reflects the status of the oscillator output frequency F.

The oscillator status signal S can be directly indicative of the output frequency F, e.g. by representing the number of pulses produced by the oscillator 2 during a chosen time interval, or be indirectly indicative of the output frequency F, e.g. by presenting a signal representing a parameter, which in turn is directly dependent on the output frequency F.

The oscillator status signal S is supplied to the comparator 15 for comparing the status signal S with a predetermined reference signal Ref. The reference signal used for this comparison could be a value, a range or a template of some sort, depending on the nature of the physiological parameter. As a result of said comparison, a deviation signal D is produced indicating whether the output frequency of the oscillator is within a permitted value or range.

Preferably, the oscillator status signal S is in the form of a value representing the output frequency F of the oscillator, and the reference signal Ref is in the form of two threshold values representing the permitted maximum and minimum frequencies of the oscillator. In such a case, the deviation signal D preferably has two possible values, the output frequency F lies within the permitted range, or the output frequency F is outside the

permitted range. According to an alternative embodiment, the oscillator status signal S represents the morphology of a physiological parameter P, e.g. heart sounds, and the comparator 15 compares the oscillator status signal S to a template using neural networks. Several other alternatives regarding the form of the oscillator status signal S and the reference signal Ref are conceivable without departing from the scope of the present invention.

According to preferred embodiments of the present invention, the physiological parameter P used for the monitoring of the status of the oscillator 2 is the electrical signal emitted by active cardiac tissue, which for ease of description hereinafter will be re10 f erred to as the cardiac signal C. The cardiac signal C is typically recorded through cardiac electrodes and the graphic depiction of the signal is normally referred to as an electrocardiogram (ECG) . If the electrodes are placed on or within the heart, the graphic depiction is referred to as an intracardiac electrogram (IEGM) . The characteristic portions of the ECG or IEGM are very well known and will be referred to without further description in detail.

The time component used for the oscillator monitoring preferably is obtained within a cardiac cycle, particularly within the systolic phase thereof. The physiological parameters could for instance be related to the width of the QRS-complex or to the QT-interval (i.e. related to the ejection phase of the heart). The parameters related to the width of the QRS-complex preferably is derived from the IEGM by means well known in the art. The parameters

related to the QT-interval may be derived directly from the IEGM or indirectly by means of pressure measurements in the ventricle, by impedance measurements, by means of heart sounds such as the valve sounds. Corresponding methods are well known in the art. Such comparison is preferably performed repeatedly for achieving a continuous monitoring of the oscillator status using the IEGM or corresponding parameters of the latest heart beat.

With reference to Figures 4 and 5, the most preferred embodiment of the present invention will now be described. The cardiac electrical activity (i.e. the cardiac signal C) is sensed through at least one cardiac electrode 22 positioned within the patient's heart. The sensed parameter is supplied, now in the form of an IEGM, to the detector 25, in this case constituting a QRS detector 26 and a T-wave detector 27 that both receives the IEGM. The QRS detector 26 detects the QRS complex, i.e. the R-peak, and the T-wave detector 27 consequently detects the T-wave. The detectors 26, 27 generate a QRS-detector output signal Q and a T-wave detection signal T, respectively, in the form of a short pulse when the respective event is detected.

The chosen time component of the physiological parameter P used for said monitoring is in this case the time period between the QRS complex and the T-wave of the IEGM, this time period hereinafter being referred to as the QT-interval. The QT-interval is relatively easy to measure and use is preferably made of the existing cardiac electrode(s) used for stimulating (and

sensing) in the ventricle for sensing the QRS complex and the T-wave. The QT-interval typically varies within the range of 250 to 350 ms and is substantially independent of the output of the main oscillator. There may he some, but very small, correlation since the QT-interval depends upon the stimulation rate. The QT-interval is therefore very useful and is preferred as the physiological parameter used for the monitoring.

Returning to Figure 4, the electric signal E, being divided into the QRS detection signal Q and a T-wave detection signal T, is supplied via a watch dog circuit 40 to the signal processing 11, the signal processing circuit here being a counter 12. The watch dog circuit 40 is provided between the detector 25 and the counter 12 for handling a specific situation and will he described in detail below with reference to Figure 5. The function of the counter 12 is as follows. The counter 12 will be reset by a QRS event, i.e. a pulse in the QRS detection signal Q. The pulse will also trigger the counter 12 to start counting received periodic pulses F produced by the main oscillator 2. At the reception of a pulse in the T-wave detection signal T, the counter 12 will stop counting and the counted number of received pulses during the QT-interval will be sent as the oscillator status signal S to the comparator 15.

The QT-interval will then be compared, by the comparator I5, with predefined QT-interval threshold values provided by a reference signal Ref, corresponding to the QT-interval at the maximum and minimum, respectively, permitted main oscillator frequency. The T-wave detection signal T is also

provided to the comparing means 15 via a delay circuit 50 for triggering the comparison. The delay circuit 50 ensures that sufficient time has elapsed for the calculation to be completed before the triggering of the comparison. The result of the comparison will he supplied as a deviation signal D indicating whether the output frequency F of the oscillator 2 lies within the permitted range.

With reference to Figure 5, the function of the watch dog circuit 40 will be described. If no signal for triggering the comparison and providing a deviation signal, i.e. the T-wave detection signal T, is provided to the comparator 15, no comparison would be carried out and the information contained in the deviation signal D would not change to describe the current status, provided that the oscillator status has changed. One attempt to solve this problem could be to perform a comparison after a given time delay without reception of the T-wave detection signal T. However, this would require some sort of timing signal to be provided. If no output pulses are received from the oscillator 2 this would not be indicated in the deviation signal U if no T-wave detection signal C for triggering the comparison is received from the T-wave detector, i.e. if the patient has no intrinsic rate.

In order to solve this potentially serious problem, the watch dog circuit 40 is provided. The watch dog circuit 40 is provided for delivering a pulse after a predetermined time in the absence of a QRS detection signal Q and a T-wave detection signal T. The circuit 40 has a first resistor 41, a second resistor 42, a transistor 43, a capacitor 44, a first buffer circuit 45, a second

buffer circuit 46, a first OR-gate 47, and a second OR-gate 48. As is apparent from Figure 5, when a QRS detection signal Q or a T-wave detection signal T, respectively, are received, these signals are supplied via the respective OR-gates 47, 48 as QRS detection signal Q^I and T-wave detection signal T^I, respectively. The respective detection signals Q, T pass through the watch dog circuit essentially unchanged, even though the output detection signals Q^I, T^I supplied to the comparing means have a difference reference character in the figure.

If there were no QRS detection signal Q, there would be no T-wave signal T. If there is a QRS signal, there will be a T-wave signal. Thus, the situation to be considered is the loss of both the QRS and the T-wave detection signals. The capacitor 44 is connected to ground and will be charged by the voltage supplied via the second resistor 42. The time constant of the circuit is dependent of the second resistor 42 and the capacitor 44. The charging of the capacitor 44 increases the potential of the side connected to the first buffer circuit 45. When the potential reaches a predefined level, the buffer circuit 45 goes high. If a QRS detection signal Q is supplied to the watch dog circuit 40, this will cause the transistor 43 to short-circuit and discharge the capacitor 44 and the potential of the first buffer circuit 45 will drop to zero before the first buffer circuit 45 goes high. However, if no QRS detection signal Q is supplied, a pulse is supplied by the first buffer circuit 45 to the first OR-gate 47 and, via the second buffer circuit 46, to the second OR-gate 48.

Then, the pulse will be supplied in place of the QRS and T-wave detection signals Q^I, T^I to the counter, with a slight delay for the T-wave detection signal T^I caused by the second buffer circuit 46, and a low pulse count, corresponding to the delay caused by the second buffer circuit 46, will be sent to the comparator 15 as the status oscillator signal S. The T-wave detection signal T^I will also trigger the comparison. Since the value of the status oscillator signal S will not lie within the predefined permitted range, the deviation signal D will indicate that the output frequency F of the oscillator has deviated from the permitted range.

According to another embodiment of the present invention the width of the QRS complex is measured and used for said monitoring. The variation of the QRS width is somewhat greater than that of the QT-interval. Like the QT-interval, this parameter can easily be measured using the cardiac electrode(s) and requires no additional electronic circuitry. Preferably, the number of output pulses from the oscillator to be monitored is counted, preferably using the counter 12 in the signal processing circuit, during the duration of 30 the QRS, and is supplied as an oscillator status signal S..

Another example of using the IEGM for the monitoring is using the paced depolarization integral (PDI). The PDI is a well-known parameter chat denotes the integral of the QRS complex of the IEGM from the base line. The PDJ essentially is constant from beat to beat. Preferably, PDJ is obtained using integrating means comprised in the signal processing circuit.

In similarity with the above embodiments, using the PDI requires no additional sensors (e.g. electrodes) or circuitry. The variation of the PDI corresponds with the QRS width, and the obtained value of the PDI is supplied as the electric signal E, as illustrated in Figure 3. Since the calculated value of the PDI varies in dependence on the output frequency F, the oscillator status signal S is based on the electric signal E, containing the PDI value, and the output frequency F. The integral is calculated by means of the output frequency and the value of the PDI will deviate from the normal value if the frequency deviates from the standard value. If the oscillator status signal S is determined to be outside predetermined threshold values, this will indicate that the oscillator frequency deviates from the permitted range.

Other physiological parameters are envisioned for monitoring the status of the main oscillator 2. According to one alternative embodiment the physiological parameter is the heart sounds or sound waves produced when the heart operates, e.g. sounds associated with valve opening and closing and diastolic filling sounds. As is the case with the characteristics of the ECG or the IEGM, the sound waves correspond to specific events in the cardiac cycle and have a characteristic morphology. Thus, the time information obtained from heart sounds is considered to be as accurate, or vary as little, as the QT-interval.

The morphology may be analyzed in several ways. According to a first example of alternative embodiments of the present invention, the

number of pulses output by the oscillator between detected specific events in the sound waves of the cardiac cycle is counted and supplied as an oscillator status signal S for subsequent comparison with threshold values Ref.

There are several ways of detecting heart sounds, including using a microphone or an accelerometer. The advantage of using an accelerometer is that accelerometers are often used in rate responsive heart stimulators for determining the level of physical activity of the patient. Thus, such an accelerometer could also be used for detecting heart sounds, and no additional sensor 10 means would be required. If the heart sounds are detected by a microphone, however, then an additional component that normally is not found in a medical implant or heart stimulator is used. There may also be a problem in detecting the heart sounds as distinctly as is required for determining the time for specific events of the cardiac cycle, due to the interference of the external environment.

According to preferred embodiments of the invention, the medical implant has back-up timing circuit (not shown), preferably an oscillator, for acting as a main timing circuit, or oscillator, when the output frequency of the original main oscillator 2 deviates outside the predefined permitted range. The back-up oscillator is preferably an RC oscillator, or a current controlled oscillator, for the purpose of providing a back-up timing source that is small and light in weight.

As is shown in Figure 1, the deviation handling circuit 30 is connected to the monitoring circuit 10, preferably to the comparator 15, for handling a deviation in the output frequency F of the main oscillator 2. The handling circuit 30 is activated when the received deviation signal U indicates a deviation, i.e. when the output frequency F deviates outside the permitted range. The handling circuit 30 contains the back-up oscillator (not shown), for producing periodic pulses normally not being used in the operation of the medical implant, and switching circuitry (not shown) connected to the main oscillator and the back-up oscillator for switching between the normal state and a deviation state. The switching between the respective state is performed by disconnecting the main oscillator 2 and by simultaneously connecting the back-up oscillator such that the periodic pulses produced in the back-up oscillator are used in the operation of the medical implant. According to preferred embodiments of the invention, the status of the back-up oscillator is also monitored by the monitoring means of the present invention, in the manner described above. However, since the back-up oscillator is normally not used for the normal function of the medical implant, the monitoring of the back-up oscillator can be per formed regularly but at a substantially lower rate than the monitoring of the main oscillator, which should be performed continuously.

According to an alternative embodiment of the invention, the deviation handling circuit 30 includes an alarm generator for providing an alarm signal when the deviation signal U indicates that the output frequency F of the

oscillator 2 deviates outside the permitted range. The alarm signal could be in the form of a signal that can be observed or sensed by the patient, e.g. an acoustic signal, or a signal that is transmitted to an external apparatus using the telemetry functions generally provided in a medical implant. The alarm signal could be provided in combination with the switching to the backup oscillator, or as a separate action, e.g. indicating that the patient should contact his/her physician but that the need for switching to the back-up oscillator has not arisen. A detected deviation in the output frequency of the back-up oscillator, when functioning as such, is preferably handled by the handling circuit 30 activating an alarm signal. Switching to the other oscillator will not be necessary since the back-up oscillator in this case is not involved in the normal operation of the medical implant.

The timing circuits used in the medical implant according to present invention are preferably oscillators, wherein as the main oscillator use is preferably made of a crystal oscillator, due to the superior reliability of crystal oscillators.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

CLAIMS

1. A medical implant (1) comprising oscillator monitoring means (10) for monitoring the function of oscillator means (2) in the medical implant (1), said oscillator means (2) producing periodic pulses for use in the operation of the medical implant (1), said oscillator monitoring means (10) detecting a deviation in said function and providing a deviation signal (D) indicating said deviation detection; and

measuring means (20) for obtaining at least one physiological parameter (P) emanating from the human body, said parameter comprising a time component, characterized in that said measuring means generates an electric signal (E) related to said time component, said oscillator monitoring means (10) being connected to the measuring means (20) for using said electric signal (E) for said deviation detection.

2. The medical implant (1) according to claim 1, wherein the monitoring means (10) comprises signal processing means (11) for processing the electric signal (E) and for generating an oscillator status signal (S), and comparing means (15) for comparing said oscillator status signal (S) with a reference signal (Ref).

3. The medical implant (1) according to claim 2, wherein said measuring means (20) comprises sensor means (21) for sensing the physiological parameter (P).

4. The medical implant (1) according to claim 3, wherein the sensor means (21) comprises cardiac electrodes (22) for receiving cardiac signals (C) emanating from cardiac electrical activity, said cardiac signals (C) constituting the physiological parameter (P) and being representative of the time component and forming an IEGM (intracardiac electrogram).

5. The medical implant (1) according to claim 4, wherein said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex and the T-wave of the IEGM, and for generating said electric signal (E), said electric signal (E) comprising a QRS detection signal (Q), and a T-wave detection signal (T).

6. The medical implant (1) according to claim 5, wherein said signal processing means (11) comprises counting means (12), said counting means (12) being connected to said detector means (25) for receiving the QRS and the T-wave detection signals (Q, Q^I, T, T^I), and to said oscillator means (2) for receiving the periodic pulses,

said counting means (12) being arranged for counting the number of periodic pulses received between the reception of the QRS detection signal (Q, Q^I) and the T-wave detection signal (T, T^I), and for outputting said number as said oscillator status signal (S).

7. The medical implant (1) according to claim 4, wherein

said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex of the IEGM, and for generating said electric signal (E), said electric signal (E) comprising a QRS signal indicating the beginning and the end of the QRS complex; and

said signal processing means (11) comprises counting means (12) connected to said detector means (25) for receiving the QRS signal, and to said oscillator means (2) for receiving the periodic pulses, said counting means (12) being arranged for counting the number of periodic pulses received between the beginning and the end of the QRS complex, and for outputting said number as said oscillator status signal (S).

8. The medical implant (1) according to claim 4, wherein

said measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting the QRS complex and the amplitude of theQRS, and for generating said electric signal (E); and

said signal processing means (11) comprises integrating means connected to said detector means (25) for receiving the electric signal (E), said integrating means being arranged for integrating said amplitude during the QRS complex, and for outputting said integration as said oscillator status signal (S).

9. The medical implant (1) according to claim 3, wherein

the sensor means (21) comprises at least one microphone for converting sensed periodic heart sounds into an electric periodic sound signal, said heart sounds constituting the physiological parameter (P);

the measuring means (20) comprises detector means (25) connected to the sensor means (21) for detecting chosen characteristics of the sound signal, and for generating said electric signal (E) indicating said characteristics; and

the signal processing means (11) is arranged for outputting said oscillator status signal (S) based on said electric signal (E).

10. The medical implant (1) according to any one of claims 2-9, wherein the reference signal (Ref) comprises predefined threshold values, and wherein the monitoring means (10) provides the deviation signal (D) indicating whether the comparing means (15) determines the oscillator status signal (S) to be outside of the threshold values, or not.

11. The medical implant (1) according to any one of the preceding claims, comprising deviation handling means for handling a deviation in said oscillator means,

said deviation handling means being connected to said monitoring means (10) for reception of said deviation signal (D).

12. The medical implant (1) according to claim 11, wherein said deviation handling means comprises

a back-up system including back-up oscillator means for producing periodic pulses, said periodic pulses in a normal state not being used in the operation of the medical implant (1), and

switching circuitry connected to said main and back-up oscillator means for switching between the normal state and a deviation state by disconnecting said oscillator means (2) and for simultaneously connecting said back-up oscillator means such that the periodic pulses produced in said back-up oscillator means are used in the operation of the medical implant.

13. The medical implant (1) according to claim 12, wherein said monitoring means (10) further is arranged for detecting a deviation in the function of said back-up oscillator means and for providing a deviation signal (D) indicating the detection of such a deviation, and wherein said deviation handling means is arranged for handling a deviation in said back-up oscillator means.

14. The medical implant (1) according to claim 12 or 13, wherein said back-up oscillator means is an RC oscillator.

15. The medical implant (1) according to any one of claims 11-14, wherein said deviation handling means comprises alarm means for producing an alarm signal when the received deviation signal (D) indicates a deviation.

16. The medical implant (1) according to any one of the preceding claims, wherein said oscillator means (2) is a crystal oscillator.

17. A method of monitoring the function of oscillator means (2) in a medical implant (1), preferably a heart stimulator, the method comprising

obtaining at least one physiological parameter (P) emanating from the human body, said physiological parameter (P) containing a time component; and

using said physiological parameter (P) in monitoring the function of said oscillator means.

18. The method according to claim 17, wherein the step of monitoring said function comprises

detecting a deviation in said function; and

providing a deviation signal (D) indicating said deviation detection.

19. The method according to claim 17 or 18, wherein the step of obtaining said physiological parameter (P) comprises

sensing said physiological parameter (P); and

generating an electric signal (E) based on said physiological parameter (P); and

wherein the step of detecting said deviation comprises

processing the electric signal (E) and thereby generating an oscillator status signal (S); and

comparing said oscillator status signal (S) with a reference signal (Ref).

20. The method according to any one of claims 17-19, wherein said physiological parameter (P) is a cardiac signal (C) emanating from cardiac electrical activity, said cardiac signals (C) being representative of the time component and forming an IEGM.

21. The method according to claim 20, wherein the step of processing the electric signal (E) comprises

detecting the QRS complex of the IEGM;

detecting the T-wave of the IEGM;

receiving periodic pulses from said oscillator means;

counting the number of received periodic pulses between said detection of the QRS complex and said detection of the T-wave; and

outputting said number as the oscillator status signal (S).

22. The method according to any one of claims 19-21, wherein said reference signal (Ref) comprises predefined threshold values; and

wherein the step of comparing said oscillator status signal (S) with a reference signal (Ref) comprises

providing a deviation signal (D) indicating whether the comparing means (15) determines the oscillator status signal (S) to be outside of the threshold values, or not.

23. The method according to any one of claims 18-22, further comprising the steps of

receiving the deviation signal (D) provided by the comparing means (15);

handling a deviation in said oscillator means (2) when the received deviation signal (D) indicates a deviation.

24. The method according to claim 23, wherein the step of handling a deviation comprises

activating a back-up system comprising back-up oscillator means for generating periodic signals, said periodic signals in an normal state not being used for the operation of the implant; and

switching between the normal state and a deviation state by disconnecting said oscillator means (2) and for simultaneously connecting said back-up oscillator means such that the periodic pulses produced in said back-up oscillator means are used in the operation of the medical implant.

25. The method according to claim 24, further comprising the steps of

detecting a deviation in the function of said back-up oscillator means and for providing a deviation signal (D) indicating detection of such a deviation; and

handling a deviation in said back-up oscillator means.

26. The method according to any one of claims 24-25, wherein the step of handling a deviation comprises activating an alarm signal.

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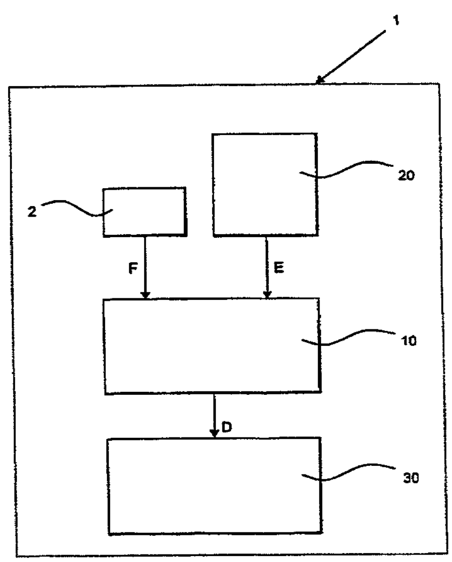

(57) Abstract: A medical implant (1) comprising oscillator monitoring means (10) for monitoring the function of an oscillator (2) in the medical implant, and a method of monitoring the function of an oscillator (2) in a medical implant (1). The oscillator (2) produces periodic pulses for use in the operation of the medical implant (1), and the oscillator monitoring means (10) detects a deviation in the function of the oscillator (2) and provides a deviation signal (D) indicating the detection of such a deviation. The medical implant (1) also comprises measuring means (20) for obtaining a physiological parameter emanating from the human body. The measuring means (20) is also provided for generating an electric signal (E) related to a time component of the physiological parameter, and the oscillator monitoring means (10) is connected to the measuring means (20) and uses the electric signal (E) for the deviation detection.

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[MEDICAL IMPLANT

Technical field of the invention]

SPECIFICATION

TITLE

"METHOD AND CIRCUIT FOR MONITORING AN OSCILLATOR IN A MEDICAL IMPLANT"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to the field of medical implants. More specifically, the present invention relates to a medical implant [comprising] of the type having an oscillator monitoring [means] circuit for monitoring the [function] functioning of an oscillator [means] in the medical implant, and a method [of] for monitoring the [function] functioning of an oscillator [means] in a medical implant, [said medical implant preferably being] such as a heart stimulator.

[Technical background and prior art]

Description of the Prior Art

For modern electronic circuits, it is generally essential to provide an accurate clocking signal in order to [synchronise] synchronize the different electronic functions of the circuit. Generally, a single master timing source, such as an oscillator, is used to produce a periodic signal at a fixed frequency. An accurate clock signal is imperative for a proper [function] functioning of the electronic circuit. If the frequency of the periodic signal

deviates from its predetermined frequency, the circuit will not function in the intended manner.

Within the field of medical implants, i.e. heart stimulators, the master timing source is generally an oscillator. Heart stimulators are life supporting, therapeutic medical devices that are surgically implanted and remain within a person's body for years. Thus, a need exists for monitoring and checking the master oscillator of the heart stimulator to determine if the frequency of the oscillator periodic signals deviates from its predetermined clock frequency and to handle such a deviation if it occurs.

[US] United States Patent No. 4,590,941 discloses a cardiac pacer [comprising] having stimulating logic for producing an output stimulating signal, the stimulating logic including a crystal oscillator and a digital circuit [for producing] serving as the pacing logic of the pacer. The pacer further [comprises] has a continuously operating RC oscillator and a frequency checking circuit. The RC oscillator is an emergency oscillator continuously producing an output at a predetermined acceptable frequency and a predetermined pulse width. The crystal frequency is tested by the frequency checking circuit using the output of the RC oscillator. The pacer further [comprises] has a gating means for substituting the output of the RC oscillator for the output of the stimulating logic upon detection of failure of the crystal oscillator.

Hence, the reference parameter used for continuously testing the frequency of the crystal oscillator is the output frequency of the RC oscillator.

This requires a continuous operation of the RC oscillator. Furthermore, the frequency checking circuit requires a reliable output from the RC oscillator in order to provide a safe and accurate result. Otherwise, the frequency of the crystal oscillator could be considered to deviate from the correct frequency when, in fact, it is the frequency of the RC oscillator that deviates from the predetermined frequency.

SUMMARY OF THE INVENTION

[Summary of the invention]

It is [therefore] an object of the present invention to provide a method, and a medical implant using [said] the method, for detecting with improved reliability a frequency deviation of the output frequency of an oscillator in a medical implant.

The above object is achieved in accordance with the principles of the present invention in a method and circuit for monitoring an oscillator in a medical implant wherein at least one physiological parameter, having a time component, is obtained from a subject in whom the medical implant is implanted, and wherein an electrical signal is generated that is related to the time component, and wherein this electrical signal is used as an indicator of a deviation of the functioning of the oscillator from an intended or specified functioning of the oscillator.

[This object is achieved in accordance with the present invention by providing a medical implant and a method having the features defined in the

independent claims. Preferred embodiments are defined in the dependent claims.]

The invention is based on using a physiological parameter emanating from the human body for monitoring the status of the output frequency of a timing circuit in a medical implant. Hence, deviations in the output frequency of the timing circuit are detected by using the physiological parameter as a reference. Preferably, the timing circuit is an oscillator.

By using a physiological parameter for detecting a deviation in the output frequency of an oscillator, use is made of a parameter that is always present, i.e. the physiological parameter can be used for detecting a frequency deviation regardless of whether there is a fault in the electronic circuitry or not. This might not always be the case when a parameter obtained from within the electronic circuitry is used for [said] the deviation detection. In fact, a deviation in the output frequency of a main oscillator in an electronic circuit, can cause resulting effects in the electronic circuitry making components within the circuitry unsuitable, or unusable, for providing a reference parameter for [said] the monitoring.

Furthermore, the problem described in relation to prior art regarding the risk of misinterpreting the result, i.e. the output frequency one oscillator being considered to deviate when the deviation occurs in the output frequency of the other oscillator, is eliminated according to the present invention. This is due to the fact that the monitoring of an oscillator does not

involve any other oscillator that might be [comprised] present in the medical implant.

The physiological parameter used for [the] monitoring [of] the output frequency of the oscillator contains a time component. The time component of the physiological parameter is used for monitoring deviation of the frequency from a permitted value or range.

As is [obvious] known to a person skilled in the art, any physiological parameter varies over time. Therefore, an exact time value can not be obtained from a physiological parameter. However, the typical oscillator used as a main oscillator in a medical implant is a crystal oscillator, which is calibrated before encapsulation [through] by mechanical [treatment] trimming. It is well known that, if the output frequency of a crystal oscillator deviates from its intended frequency, it deviates drastically, the output frequency for instance changing to zero or multiples of the intended frequency. Thus, a physiological parameter can be used for monitoring the status of an oscillator, even though [said] the parameter varies slightly over time.

[Further details and aspects of the invention will become apparent from the following detailed description of embodiments of the invention, reference being made to the accompanying drawings.

Brief description of the drawings]

DESCRIPTION OF THE DRAWINGS

Figure 1 [illustrates in] is a block diagram [form] of a medical implant [comprising] having an oscillator monitoring [means] circuit according to the present invention.

Figure 2 [illustrates in] is a block diagram [form] of the measuring [means] circuit shown in [figure] Figure 1.

Figure 3 [illustrates in] is a block diagram [form] of the monitoring [means] circuit shown in [figure] Figure 1.

Figure 4 [illustrates in] is a block diagram [form] of a specific embodiment of the present invention.

Figure 5 [illustrates in] is a block diagram [form] of a watch dog circuit according to the embodiment shown in [figure] Figure 4.

[Detailed description of preferred embodiments]

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[With reference to figure 1., there is shown in] Figure 1 is a block diagram [form] of a medical implant 1 [comprising] having an oscillator 2, an oscillator monitoring [means] circuit 10, a measuring [means] circuit 20 and a deviation handling [means] circuit 30. As is apparent to the person skilled in the art, a medical implant, i.e. a heart stimulator, [comprises] contains and is connected to a number of additional elements that are essential for the in tended function of the implant, e.g. a pulse generator, telemetry means, etc. However, the functions of these elements are well known within the art and the illustration and description thereof are therefore omitted. Thus, only

parts of the medical implant directly related to the present invention are illustrated and described herein.

As illustrated in [figure] Figure 2, the measuring [means] circuit 20 preferably [comprises] has a sensor [means] 21, for sensing, or recording, a chosen physiological parameter P, and [detecting means] a detector 25[,] for detecting characteristics of the chosen physiological parameter P. The sensor type can be chosen among several alternatives and is dependent on the chosen physiological parameter P. The sensor [means] 21 is connected to the [detecting means] detector 25, but is not necessarily contained within the medical implant 1, contrary to what is illustrated in [figure] Figure 1. According to embodiments of the invention, the sensor [means] 21 is situated externally of the medical implant and is connected to the medical implant [through] via electric leads 20 (not shown).

The [detecting means] detector 25 is arranged for detecting characteristics of the physiological parameter P [comprising] having the chosen time component, the characteristics being dependent on the type of parameter sensed, and for generating an electric signal E containing or being related to these characteristics. The sensor [means] 21 and the detector [means] 25 do not necessarily have to be separate units, instead they can be [comprised] formed as a single unit for sensing the physiological parameter P and for generating the electric signal B.

With reference to [figure] Figure 3, the oscillator monitoring [means] circuit 10 preferably [comprises] has a signal processing [means] circuit 11,

receiving the electric signal E and oscillator output frequency F (i.e. the periodic pulses produced by the oscillator), and [comparing means] comparator I5, receiving an oscillator status signal S supplied by the signal processing [means] circuit 11 and a predetermined reference signal Ref, which can be in the form of a value, range, or a template. Preferably, the electric signal B representative of the physiological parameter P is used by the signal processing [means] circuit 11 for generating an oscillator status signal S that reflects the status of the oscillator output frequency F.

The oscillator status signal S can be directly indicative of the output frequency F, e.g. by representing the number of pulses produced by the oscillator 2 during a chosen time interval, or be indirectly indicative of the output frequency F, e.g. by presenting a signal representing a parameter, which in turn is directly dependent on the output frequency F.

The oscillator status signal S is supplied to the [comparing means] comparator 15 for comparing the status signal S with a predetermined reference signal Ref. The reference signal used for [said] this comparison could be a value, a range or a template of some sort, depending on the nature of the physiological parameter. As a result of said comparison, a deviation signal D is produced indicating whether the output frequency of the oscillator is within a permitted value or range[, or not].

Preferably, the oscillator status signal S is in the form of a value representing the output frequency F of the oscillator, and the reference signal Ref is in the form of two threshold values representing the permitted

maximum and minimum frequencies of the oscillator. In such a case, the deviation signal D preferably has two possible values, the output frequency F lies within the permitted range, or the output frequency F is outside the permitted range. According to an alternative embodiment, the oscillator status signal S represents the morphology of a physiological parameter P, e.g. heart sounds, and the [comparing means] comparator 15 compares the oscillator status signal S to a template using neural networks. Several other alternatives regarding the form of the oscillator status signal S and the reference signal Ref are conceivable without departing from the scope of the present invention.

According to preferred embodiments of the present invention, the physiological parameter P used for the monitoring of the status of the oscillator 2 is the electrical signal emitted by active cardiac tissue, which for ease of description hereinafter will be re10 f erred to as the cardiac signal C. The cardiac signal C is typically recorded through cardiac electrodes and the graphic depiction of the signal is normally referred to as an electrocardiogram (ECG) . If the electrodes are placed on or within the heart, the graphic depiction is referred to as an intracardiac electrogram (IEGM) . The characteristic portions of the ECG or IEGM are very well known and will be referred to without further description in detail.

The time component used for the oscillator monitoring preferably is obtained within a cardiac cycle, particularly within the systolic phase thereof. The physiological parameters could for instance be related to the width of the

QRS-complex or to the QT-interval (i.e. related to the ejection phase of the heart). The parameters related to the width of the QRS-complex preferably is derived from the IEGM by means well known in the art. The parameters related to the QT-interval may be derived directly from the IEGM or indirectly by means of pressure measurements in the ventricle, by impedance measurements, by means of heart sounds such as the valve sounds. Corresponding methods are well known in the art. [Said] <u>Such</u> comparison is preferably performed repeatedly for achieving a continuous monitoring of the oscillator status using the IEGM or corresponding parameters of the latest heart beat.

With reference to [figures] <u>Figures</u> 4 and 5, the most preferred embodiment of the present invention will now be described. The cardiac electrical activity (i.e. the cardiac signal C) is sensed through at least one cardiac electrode 22 positioned within the patient's heart. The sensed parameter is supplied, now in the form of an IEGM, to the [detecting means] <u>detector</u> 25, in this case constituting a QRS detector 26 and a T-wave detector 27 that both receives the IEGM. The QRS detector 26 detects the QRS complex, i.e. the R-peak, and the T-wave detector 27 consequently detects the T-wave. The detectors 26, 27 generate a QRS-detector output signal Q and a T-wave detection signal T, respectively, in the form of a short pulse when the respective event is detected.

The chosen time component of the physiological parameter P used for said monitoring is in this case the time period between the QRS complex

and the T-wave of the IEGM, [said] this time period hereinafter being referred to as the QT-interval. The QT-interval is relatively easy to measure and use is preferably made of the existing cardiac electrode(s) used for stimulating (and sensing) in the ventricle for sensing the QRS complex and the T-wave. The QT-interval typically varies within the range of 250 to 350 ms and is substantially independent of the output of the main oscillator. There may he some, but very small, correlation since the QT-interval depends upon the stimulation rate. The QT-interval is therefore very useful and is preferred as the physiological parameter used for [said] the monitoring.

Returning to [figure] Figure 4, the electric signal E, being divided into the QRS detection signal Q and a T-wave detection signal T, is supplied via a watch dog circuit 40 to the signal processing 11, the signal processing [means] circuit 11 here being a counter 12. The watch dog circuit 40 is provided between the [detecting means] detector 25 and the counter 12 for handling a specific situation and will he described in detail below with reference to [figure] Figure 5. The function of the counter 12 is as follows. The counter 12 will be reset by a QRS event, i.e. a pulse in the QRS detection signal Q. The pulse will also trigger the counter 12 to start counting received periodic pulses F produced by the main oscillator 2. At the reception of a pulse in the T-wave detection signal T, the counter 12 will stop counting and the counted number of received pulses during the QT-interval will be sent as the oscillator status signal S to the [comparing means] comparator 15.

The QT-interval will then be compared, by the [comparing means] comparator l5, with predefined QT-interval threshold values provided by a reference signal Ref, corresponding to the QT-interval at the maximum and minimum, respectively, permitted main oscillator frequency. The T-wave detection signal T is also provided to the comparing means 15 via a delay circuit 50 for triggering [said] the comparison. The delay circuit 50 ensures that sufficient time has elapsed for the calculation to be completed before the triggering of the comparison. The result of the comparison will he supplied as a deviation signal D indicating whether the output frequency F of the oscillator 2 lies within the permitted range[, or not].

With reference [now] to [figure] Figure 5, the function of the watch dog circuit 40 will be described. If no signal for triggering the comparison and providing a deviation signal, i.e. the T-wave detection signal T, is provided to the [comparing means] comparator 15, no comparison would be carried out and the information contained in the deviation signal D would not change to describe the current status, provided that the oscillator status has changed. One attempt to solve this problem could be to perform a comparison after a given time delay without reception of the T-wave detection signal T. However, this would require some sort of timing signal to be provided. If no output pulses are received from the oscillator 2 this would not be indicated in the deviation signal U if no T-wave detection signal C for triggering the comparison is received from the T-wave detector, i.e. if the patient has no intrinsic rate.

In order to solve this potentially serious problem, the watch dog circuit 40 is provided. The watch dog circuit 40 is provided for delivering a pulse after a predetermined time in the absence of a QRS detection signal Q and a T-wave detection signal T. The circuit 40 [comprises] has a first resistor 41[;], a second resistor 42[;], a transistor 43[;], a capacitor 44[;], a first buffer circuit 45[;], a second buffer circuit 46[;], a first OR-gate 47[;], and a second OR-gate 48. As is apparent from [the figure] Figure 5, when a QRS detection signal Q or a T-wave detection signal T, respectively, are received, these signals are supplied via the respective OR-gates 47, 48 as QRS detection signal Q^I and T-wave detection signal T^I, respectively. The respective detection signals Q, T [passes] pass through the watch dog circuit essentially unchanged, even though the output detection signals Q^I, T^I supplied to the comparing means have a difference reference character in the figure.

If there [would be a] were no QRS detection signal Q, there would be no T-wave signal T. If there is a QRS signal, there will be a T-wave signal. Thus, the situation to be considered is the loss of both the QRS and the T-wave detection signals. The capacitor 44 is connected to ground and will be charged by the voltage supplied via the second resistor 42. The time constant of the circuit is dependent of the second resistor 42 and the capacitor 44. The charging of the capacitor 44 increases the potential of the side connected to the first buffer circuit 45. When the potential reaches a predefined level, the buffer circuit 45 goes high. If a QRS detection signal

Q is supplied to the watch dog circuit 40, this will cause the transistor 43 to short-circuit and discharge the capacitor 44 and the potential of the first buffer circuit 45 will drop to zero before the first buffer circuit 45 goes high. However, if no QRS detection signal Q is supplied, a pulse is supplied by the first buffer circuit 45 to the first OR-gate 47 and, via the second buffer circuit 46, to the second OR-gate 48.

Then, the pulse will be supplied in place of the QRS and T-wave detection signals Q^I, T^I to the counter, with a slight delay for the T-wave detection signal T^I caused by the second buffer circuit 46, and a low pulse count, corresponding to the delay caused by the second buffer circuit 46, will be sent to the [comparing means] comparator 15 as the status oscillator signal S. The T-wave detection signal T^I will also trigger the comparison. Since the value of the status oscillator signal S will not lie within the predefined permitted range, the deviation signal D will indicate that the output frequency F of the oscillator has deviated from the permitted range.

According to another embodiment of the present invention the width of the QRS complex is measured and used for said monitoring. The variation of the QRS width is somewhat greater than that of the QT-interval. Like the QT-interval, this parameter can easily be measured using the cardiac electrode(s) and requires no additional electronic circuitry. Preferably, the number of output pulses from the oscillator to be monitored is counted, preferably using [counting means] the counter 12 [comprised] in

the signal processing [means] circuit 11, during the duration of 30 the QRS, and is supplied as an oscillator status signal S..

Another example of using the IEGM for [said] the monitoring is using the paced [depolarization] depolarization integral (PDI). The PDI is a well-known parameter chat denotes the integral of the QRS complex of the IEGM from the base line. The PDJ essentially is constant from beat to beat. Preferably, PDJ is obtained using integrating means comprised in the signal processing [means] circuit 11. In similarity with the above embodiments, using the PDI requires no additional sensors (e.g. electrodes) or circuitry. The variation of the PDI corresponds with the QRS width, and the obtained value of the PDI is supplied as the electric signal E, as illustrated in [figure] Figure 3. Since the calculated value of the PDI varies in dependence on the output frequency F, the oscillator status signal S is based on the electric signal E, [comprising] containing the PDI value, and the output frequency F. The integral is calculated by means of the output frequency and the value of the PDI will deviate from the normal value if the frequency deviates from the standard value. If the oscillator status signal S is determined to be outside predetermined threshold values, this will indicate that the oscillator frequency deviates from the permitted range.

Other physiological parameters are envisioned for monitoring the status of the main oscillator 2. According to one alternative embodiment the physiological parameter is the heart sounds or sound waves produced when the heart operates, e.g. sounds associated with valve opening and closing

and diastolic filling sounds. As is the case with the characteristics of the ECG or the IEGM, the sound waves correspond to specific events in the cardiac cycle and have a characteristic morphology. Thus, the time information obtained from heart sounds is considered to be as accurate, or vary as little, as the QT-interval.

The morphology may be [analysed] <u>analyzed</u> in several ways. According to a first example of alternative embodiments of the present invention, the number of pulses output by the oscillator between detected specific events in the sound waves of the cardiac cycle is counted and supplied as an oscillator status signal S for subsequent comparison with threshold values Ref.

There are several ways of detecting heart sounds, including using a microphone or an accelerometer. The advantage of using an accelerometer is that accelerometers are often used in rate responsive heart stimulators for determining the level of physical activity of the patient. Thus, such an accelerometer could also be used for detecting heart sounds, and no additional sensor 10 means would be required. If the heart sounds are detected by a microphone, however, then an additional component that normally is not found in a medical implant or heart stimulator is used. There may also be a problem in detecting the heart sounds as distinctly as is required for determining the time for specific events of the cardiac cycle, due to the interference of the external environment.

According to preferred embodiments of the invention, the medical implant [comprises] has a back-up timing circuit (not shown), preferably an oscillator, for acting as a main timing circuit, or oscillator, when the output frequency of the original main oscillator 2 deviates outside the predefined permitted range. The back-up oscillator is preferably an RC oscillator, or a current controlled oscillator, for the purpose of providing a back-up timing source that is small and light in weight.

As is shown in [figure] Figure 1, the deviation handling [means] circuit 30 is connected to the monitoring [means] circuit 10, preferably to the [comparing means] comparator 15, for handling a deviation in the output frequency F of the main oscillator 2. The handling [means] circuit 30 is activated when the received deviation signal U indicates a deviation, i.e. when the output frequency F deviates outside the permitted range. The handling [means] circuit 30 [comprises] contains the back-up oscillator (not shown), for producing periodic pulses normally not being used in the operation of the medical implant, and switching circuitry (not shown) connected to the main oscillator and the back-up oscillator for switching between the normal state and a deviation state. The switching between the respective state is performed by disconnecting the main oscillator 2 and by simultaneously connecting the back-up oscillator such that the periodic pulses produced in the back-up oscillator are used in the operation of the medical implant. According to preferred embodiments of the invention, the status of the back-up oscillator is also monitored by the monitoring means

of the present invention, in the manner described above. However, since the back-up oscillator is normally not used for the normal function of the medical implant, the monitoring of the back-up oscillator can be per formed regularly but at a substantially lower rate than the monitoring of the main oscillator, which should be performed continuously.

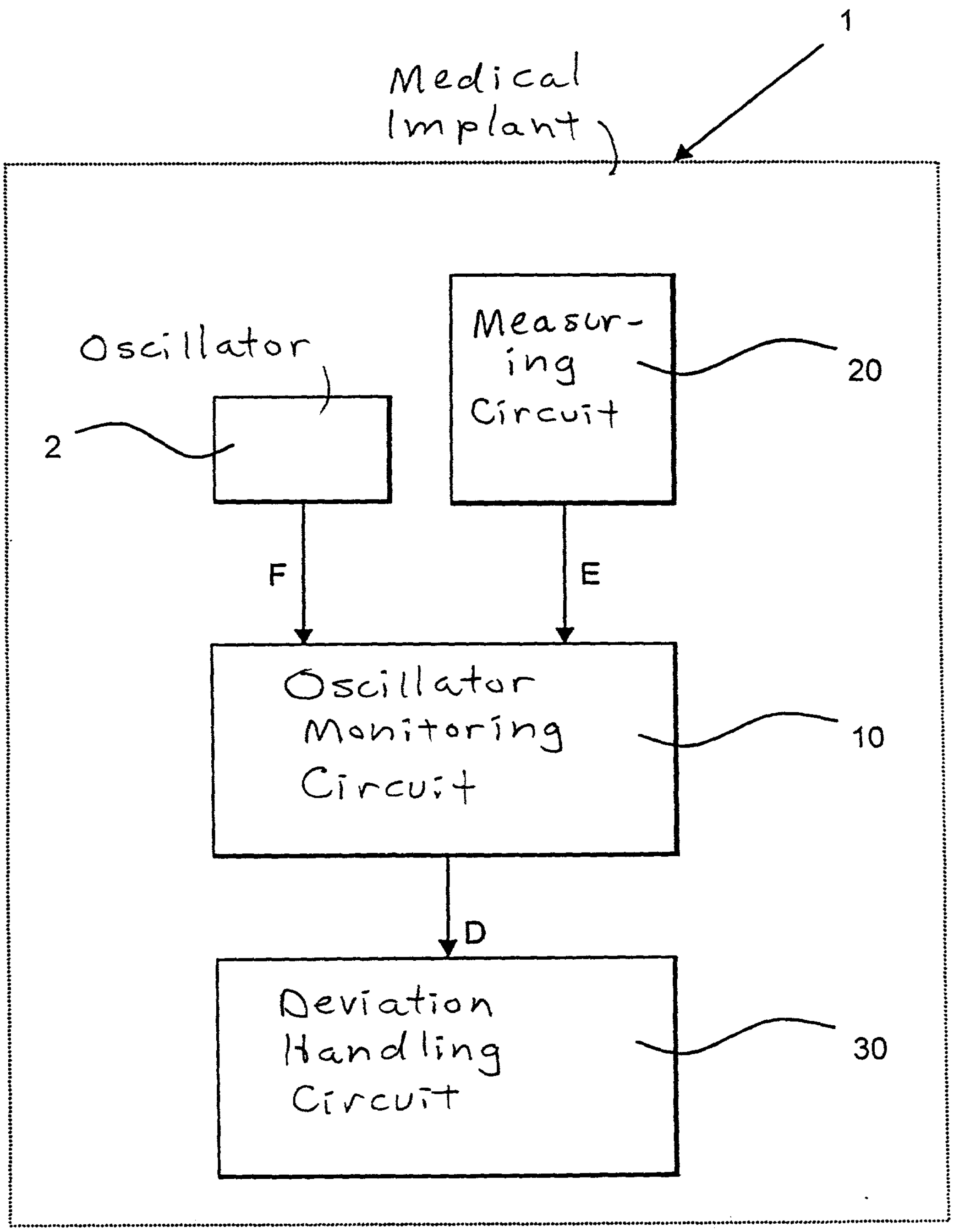
According to an alternative embodiment of the invention, the deviation handling [means] circuit 30 [comprises] includes an alarm [means] generator for providing an alarm signal when the deviation signal U indicates that the output frequency F of the oscillator 2 deviates outside the permitted range. The alarm signal could be in the form of a signal that can be observed or sensed by the patient, e.g. an acoustic signal, or a signal that is transmitted to an external apparatus using the telemetry functions generally provided in a medical implant. The alarm signal could be provided in combination with [said] the switching to the backup oscillator, or as a separate action, e.g. indicating that the patient should contact his/her physician but that the need for switching to the back-up oscillator has not arisen. A detected deviation in the output frequency of the back-up oscillator, when functioning as such, is preferably handled by the handling [means] circuit 30 activating an alarm signal. Switching to the other oscillator will not be necessary since the back-up oscillator in this case is not involved in the normal operation of the medical implant.

The timing circuits used in the medical implant according to present invention are preferably oscillators, wherein as the main oscillator use is

preferably made of a crystal oscillator, due to the superior reliability of crystal oscillators.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

Fig. 1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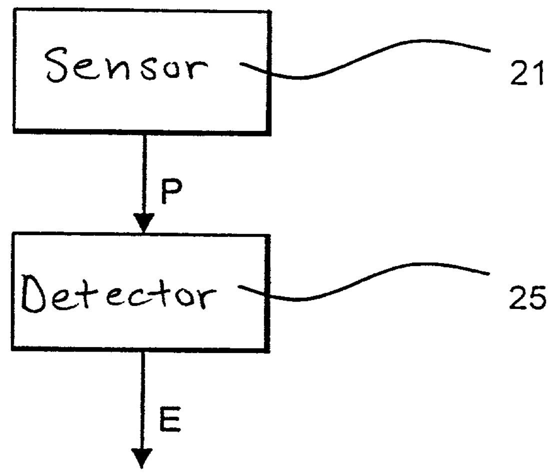
2
Measuring Circuit
20
F
E
Oscillator Monitoring Circuit
10
D
Deviation Handling Circuit
30

Fig. 2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Detector
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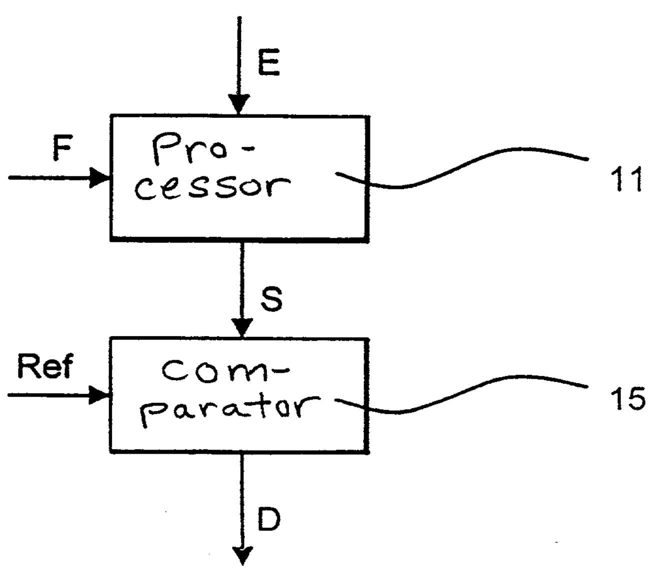
Fig. 3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S
Ref
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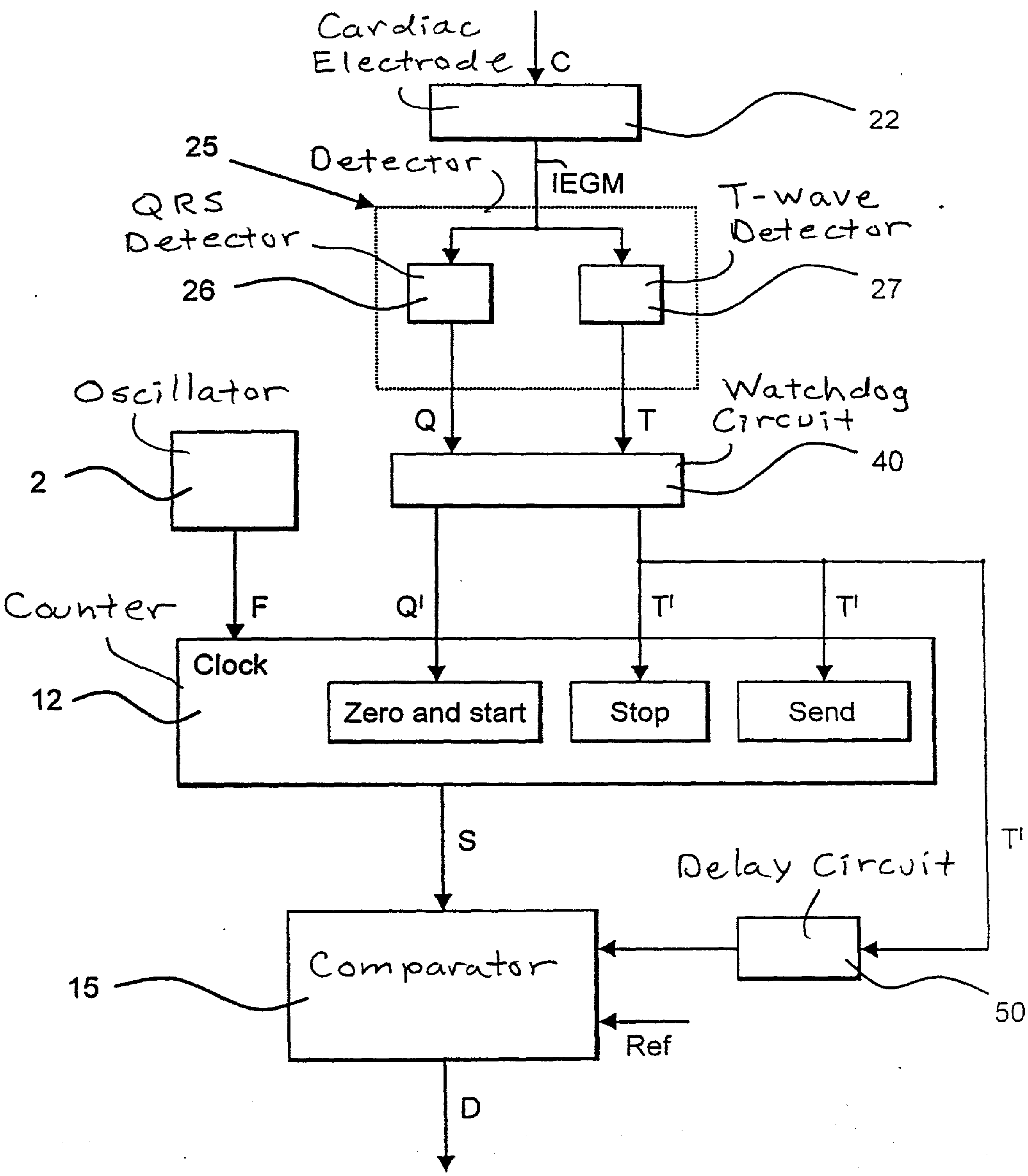
15
D

Fig. 4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IEGM
QRS Detector
T-wave Detector
26
27
Oscillator
Q
T
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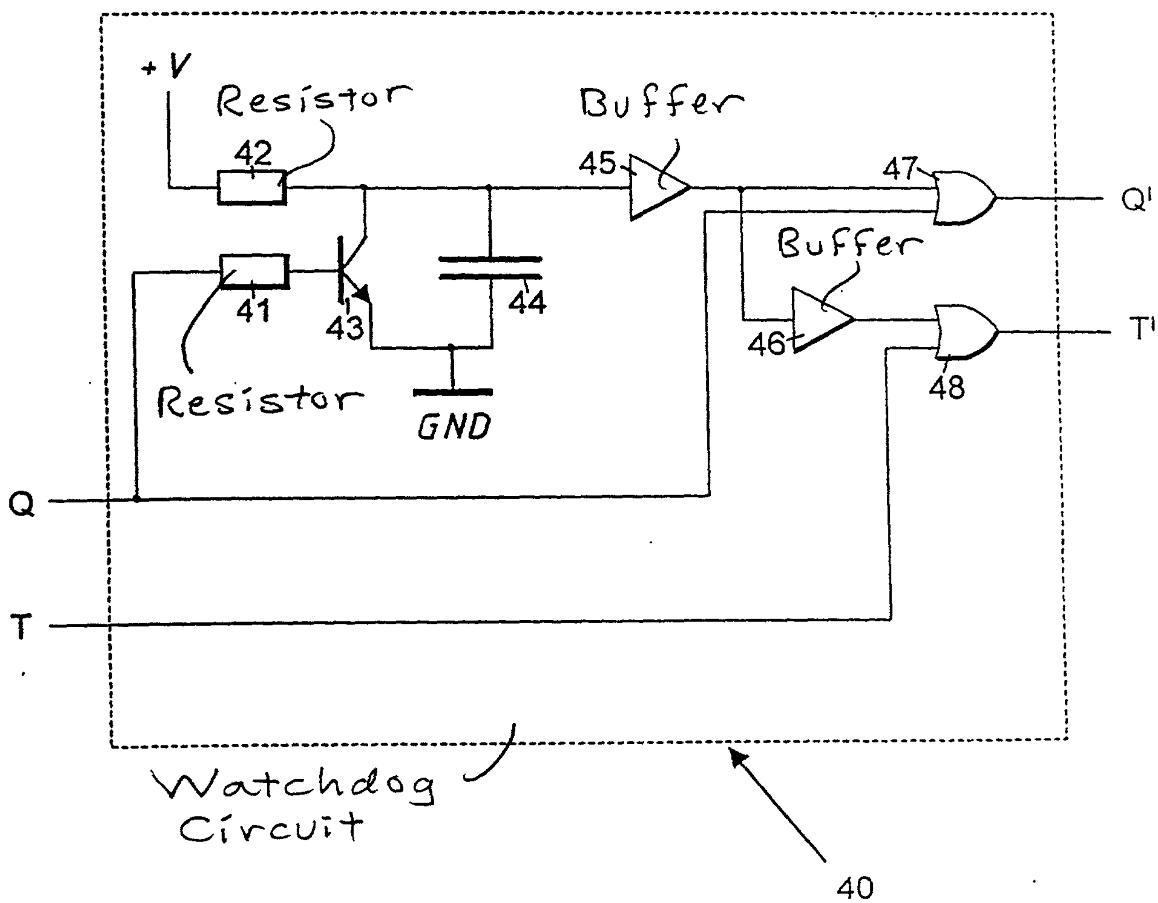
40
2
Counter
F
Q'
T'
T'
12
Clock
Zero and start
Stop
Send
S
T'
Delay Circuit
Comparator
15
50
Ref
D

Fig.5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47
Q'
Buffer
41
43
44
46
T'
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Q
T
Watchdog
Circuit
40

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BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

REQUEST FOR APPROVAL OF DRAWING CHANGES

APPLICANTS:	Hedberg et al.
ATTORNEY DOCKET NO.	P01,0442
INTERNATIONAL APPLICATION NO:	PCT/SE00/01025
INTERNATIONAL FILING DATE:	May 22, 2000
INVENTION:	"METHOD AND CIRCUIT FOR MONITORING AN OSCILLATOR IN A MEDICAL IMPLANT" (AS AMENDED)

Assistant Commissioner for Patents,

Washington, D.C.

S I R:

Applicants herewith request approval of the drawing changes in each of Figures 1, 2, 3, 4 and 5, as shown on the drawing copies marked in red attached hereto.

Submitted by,

Steven H. Noll (Reg. 28,982)

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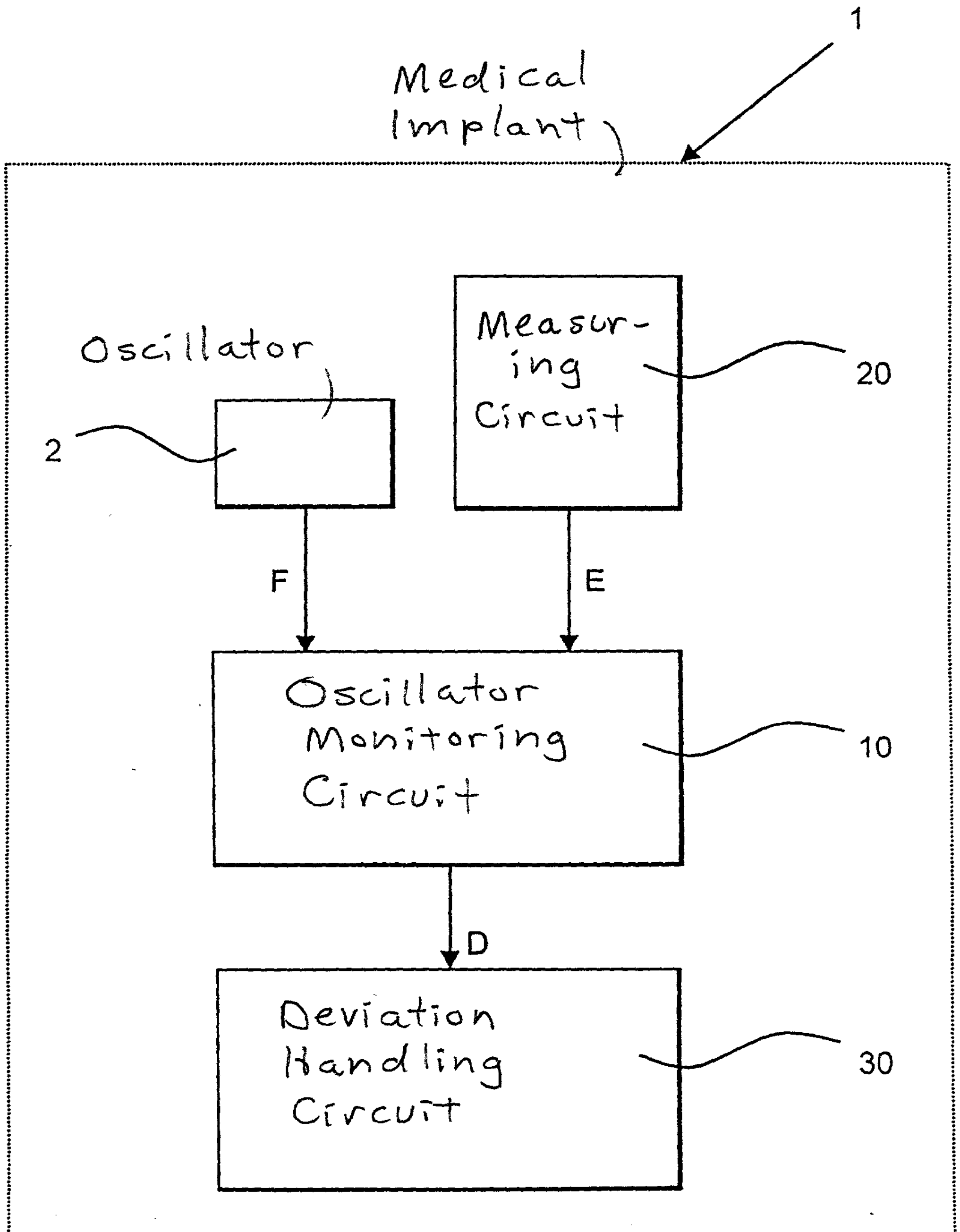
Fig. 1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Oscillator
2
Measuring Circuit
20
F
E
Oscillator Monitoring Circuit
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D
Deviation Handling Circuit
30

Fig. 2

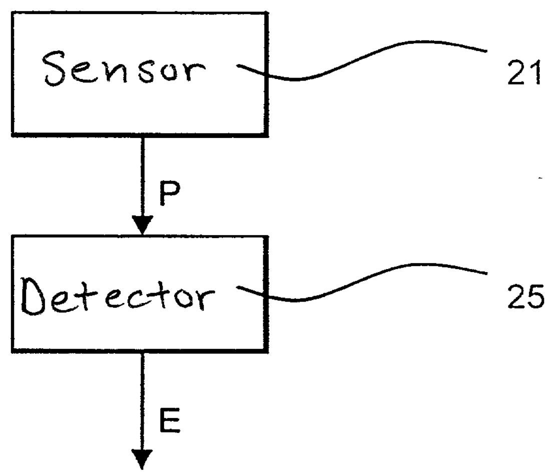
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Fig. 3

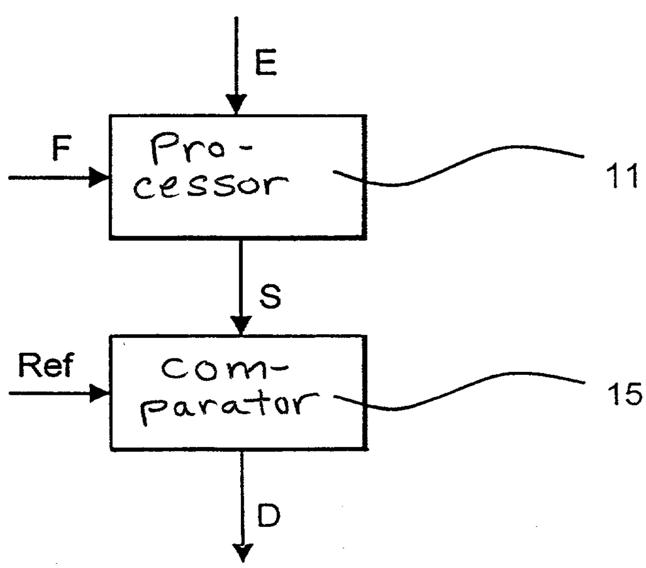
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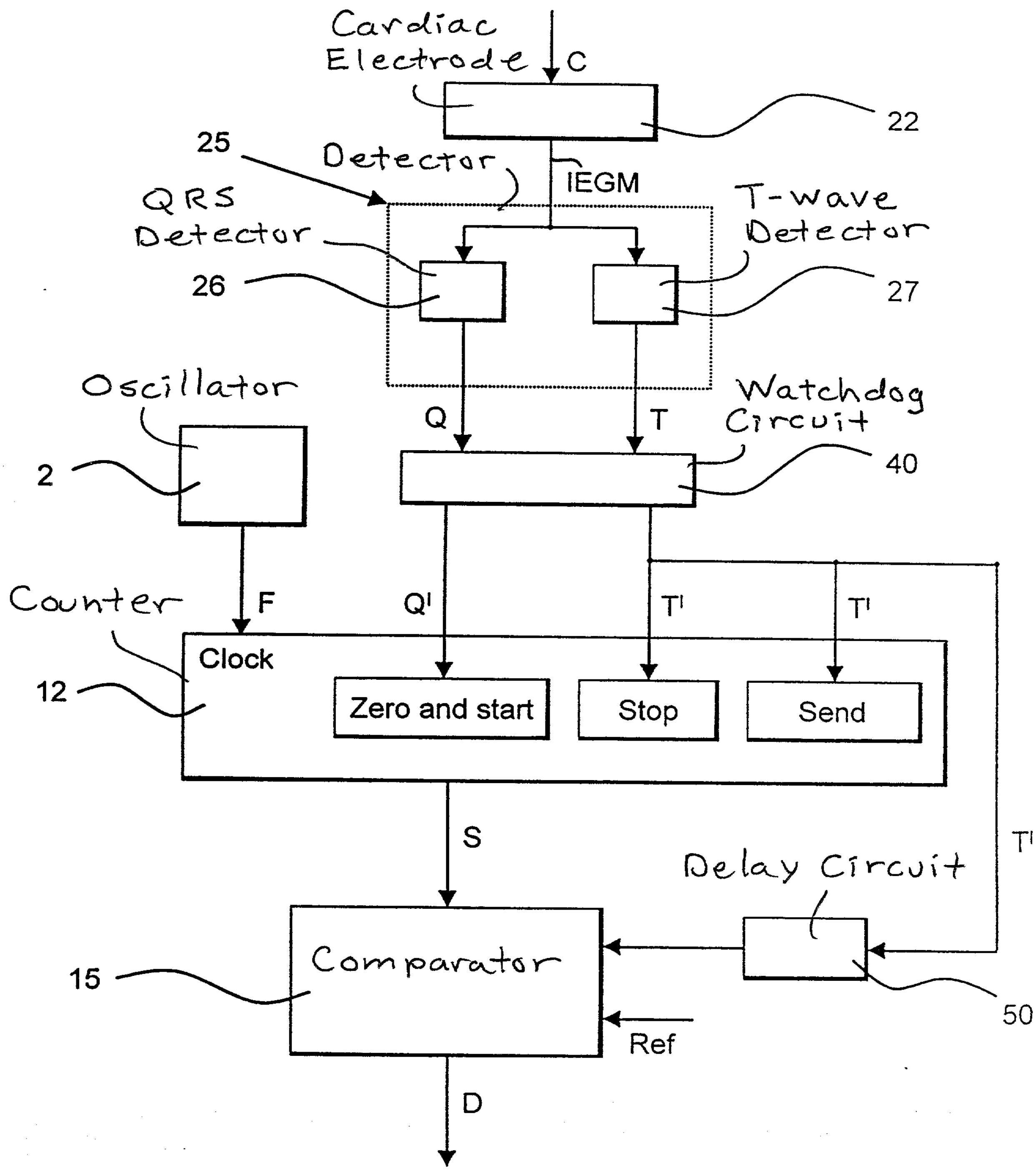
Fig. 4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Watchdog Circuit
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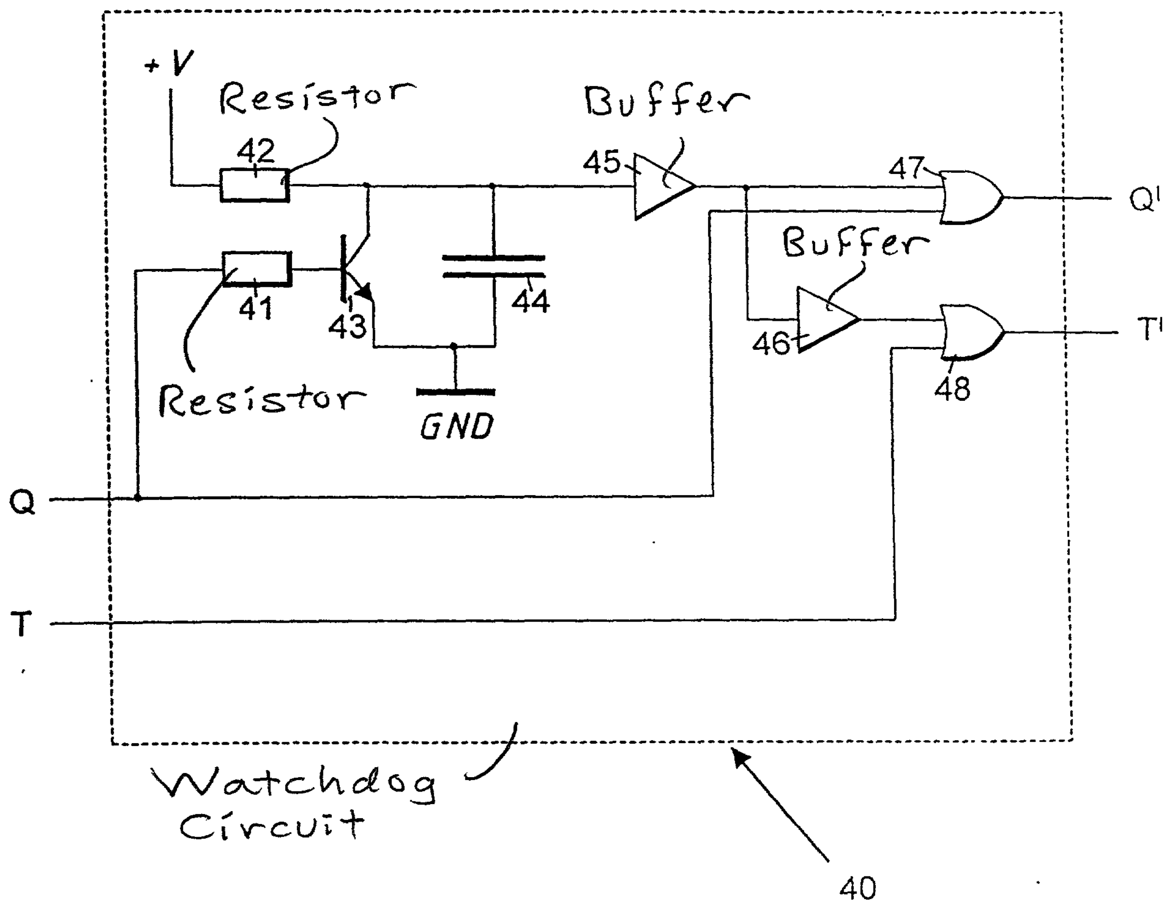
2
40
Counter
F
Q'
T'
T'
Clock
12
Zero and start
Stop
Send
S
T'
Delay Circuit
Comparator
15
50
Ref
D

Fig.5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42
Buffer
45
47
Q'
Buffer
41
43
44
46
T'
48
Resistor
GND
Q
T
Watchdog Circuit
40

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NUMBER P01,0442

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:
"METHOD AND CIRCUIT FOR MONITORING AN OSCILLATOR IN A MEDICAL IMPLANT" (AS AMENDED)
the specification of which (check only one item below):

☐ is attached hereto.

■ was filed as United States application
Serial No. 10/009,469

on December 3, 2001,

and was amended

on December 3, 2001 (if applicable).

☐ was filed as PCT international application

Number ______

on ______,

and was amended under PCT Article 19

on ______ (if applicable).

I hereby state that I have reviewed and understand the contest of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
SWEDEN	9902058-8	03.06.99	■ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

Combined Declaration For Patent Application and Power of Attorney (Continued) (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NO. P01,0442

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject mater of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, Untied States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.			STATUS (Check one)		
PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)	PATENTED	PENDING	ABANDONED

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

And I hereby appoint all Attorneys identified by the United States Patent & Trademark Office Customer Number 26574, who are all members of the firm of Schiff, Hardin & Waite.

Send Correspondence to:	SCHIFF, HARDIN & WAITE Patent Department 6600 Floor Sears Tower, Chicago, Illinois 60606 Customer Number 26574	Direct Telephone Calls to: 312/258-5790

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	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE April 19, 2002	DATE April 16, 2002	DATE